UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,377	01/23/2004	Yat Sun Or	ENP-074 (4014.1074 US)	7571

38473 7590 11/22/2005

ELMORE PATENT LAW GROUP, PC
209 MAIN STREET
N. CHELMSFORD, MA 01863

EXAMINER	
KRISHNAN, GANAPATHY	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/763,377	OR, YAT SUN	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/05;10/04;9/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 8 is objected to because of the following informalities: The proper Markush language, "selected from the group consisting of" should be recited in claim 8. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-12 recite the limitations "X and Y; C=O, C=NH, C=N-OH, C=N-NH2; R_g, R_e, R_f, U, V" in claim 4. There is insufficient antecedent basis for these limitations in the claim. It appears that Claims 7-12 recite limitations drawn to structures in Claim 5. For the purpose of prosecution it is interpreted that claims 7-12 depend from claim 5.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 4-6, 10, 12 and 13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 12 and 13 of copending Application No. 10/946339 ('339 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claim 13 is drawn to a bridged macrocyclic product. It is a product-by-process claim, which is a product claim. Claims 1-7 of the copending '339 application are also drawn to a bridged macrocyclic product.

Instant claim 1 is drawn to a process for preparing a bridged macrocyclic product via reaction of a macrocyclic compound having at least two nucleophilic moieties with a bridging component. Dependent claims 2, 4-6, 10 and 12 recite limitations drawn to specifc macrolides and structural formulae with specific structural requirements.

Claims 12 and 13 are also drawn to a process for the preparation of a bridged macrocyclic product comprising reaction of a macrolide antibiotic (azithromycin) having at least two nucleophilic groups with a bridging component (a diester). The starting material (Ia) in copending claim 12 has all of the structural features seen in instant claims 1-2, 4-6, 10 and 12.

It would be obvious to one of ordinary skill in the art that instant claims 1-2, 4-6, 10, 12 and 13 are substantially overlapping with claims 1-7, 12 and 13 of the copending '339 application since both are drawn to product with same structural features and the process of the instant claims 1-2, 4-6, 10 and 12 are broad and encompass the process steps recited in the

copending claims and are applicable for making a bridged macrocyclic compound as instantly claimed.

Claims 1-2, 4-6, 8-10 and 13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 and 8 of copending Application No. 10/840949 ('949 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claim 1 is drawn to a process for preparing a bridged macrocyclic product via reaction of a macrocyclic compound having at least two nucleophilic moieties with a bridging component. Dependent claims 2, 4-6, 10 and 12 recite limitations drawn to specifc macrolides and structural formulae with specific structural requirements.

Claim 8 of the copending application is also drawn to a process for the preparation of a bridged macrocyclic product comprising reaction of a macrolide antibiotic (azithromycin) having at least two nucleophilic groups with a bridging component (a diester). The starting material (II) in copending claim 8 has all of the structural features seen in instant claims 1-2, 4-6, 10 and 12.

It would be obvious to one of ordinary skill in the art that instant claims 1-2, 4-6, 8-10 and 13 are substantially overlapping with claims 1-5 and 8 of the copending '949 application since both are drawn to a product with same structural features and the process of the instant claims 1-2, 4-6, 8-10 and 13 are broad and encompass the process steps recited in the copending claims and are applicable for making a bridged macrocyclic compound as instantly claimed.

Claims 1-6, 8-10 and 12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 10/758409 ('409 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claim 1 is drawn to a process for preparing a bridged macrocyclic product via reaction of a macrocyclic compound having at least two nucleophilic moieties with a bridging component. Dependent claims 2, 4-6, 10 and 12 recite limitations drawn to specifc macrolides and structural formulae with specific structural requirements.

Claims 1-4 of the copending '409 application are also drawn to a process for the preparation of a bridged macrocyclic product comprising reaction of a macrolide antibiotic (derivative of azithromycin) having at least two nucleophilic groups with a bridging component (a diester). The starting material (formula I) in copending claim 1 has all of the structural features seen in instant claims 1-6, 8-10 and 12.

It would be obvious to one of ordinary skill in the art that instant claims 1-6, 8-10 and 12 are substantially overlapping with claims 1-4 of the copending '409 application since both are drawn to a product with same structural features and the process of the instant claims 1-6, 8-10 and 12 are broad and encompass the process steps recited in copending claims 1-4 and are applicable for making a bridged macrocyclic compound as instantly claimed.

Claims 1-6 and 8-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11, 15, 17-21 and 23-28

of copending Application No. 10/436622 ('622 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claim 1 is drawn to a process for preparing a bridged macrocyclic product via reaction of a macrocyclic compound having at least two nucleophilic moieties with a bridging component. Dependent claims 2-6 and 8-12 recite limitations drawn to specifc macrolides and structural formulae with specific structural requirements.

Claim 15 of the copending '622 application is also drawn to a process for the preparation of a bridged macrocyclic product comprising reaction of a macrolide antibiotic (derivative of erythromycin) having at least two nucleophilic groups with a bridging component (an ester-ether). The starting material (formula 1-2) in copending claim 15 has all of the structural features seen in instant claims 1-6, 8-12.

Instant claim 13 is drawn to a bridged macrocyclic product obtained by the instant process. It is a product-by-process claim, which is a product claim.

Claims 1-11, 17-21 and 23-28 of the copending '622 application are also drawn to a bridged macrocyclic product.

It would be obvious to one of ordinary skill in the art that instant claims 1-6, 8-12 and 13 are substantially overlapping with claims 1-11, 15, 17-21 and 23-28 of the copending '622 application since both are drawn to a product with same structural features and the process of the instant claims 1-6 and 8-12 are broad and encompass the process steps recited in copending claim 15 and are applicable for making a bridged macrocyclic compound as instantly claimed.

Claims 1-6 and 8-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 and 37-40 of copending Application No. 11/008581 ('581 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claim 1 is drawn to a process for preparing a bridged macrocyclic product via reaction of a macrocyclic compound having at least two nucleophilic moieties with a bridging component. Dependent claims 2-6 and 8-12 recite limitations drawn to specifc macrolides and structural formulae with specific structural requirements.

Claims 37-40 of the copending '581 application are also drawn to a process for the preparation of a bridged macrocyclic product comprising reaction of a macrolide antibiotic (derivative of erythromycin) having at least two nucleophilic groups with a bridging component (a bis carbonate). The starting material in copending claim 37 has all of the structural features seen in instant claims 1-6 and 8-12.

Instant claim 13 is drawn to a bridged macrocyclic product obtained by the instant process. It is a product-by-process claim, which is a product claim.

Claims 1-22 of the copending '581 application are also drawn to a bridged macrocyclic product.

It would be obvious to one of ordinary skill in the art that instant claims 1-6 and 8-13 are substantially overlapping with claims 1-22 and 37-40 of the copending '581 application since both are drawn to a product with same structural features and the process of instant claims 1-6 and 8-12 are broad and encompass the process steps recited in copending claims 37-40 and are applicable for making a bridged macrocyclic compound as instantly claimed.

Instant claims 1-13 must recite limitations that are patentably distinct from those of the claims of the copending applications cited above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 13 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,878,691 ('691 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claim 13 is drawn to a bridged macrocyclic product obtained by the instant process. It is a product-by-process claim, which is a product claim.

Claims 1-8 of the '691 patent are also drawn to a bridged macrocyclic product that are embraced by the bridged macrocyclic product of instant claim 13.

It would be obvious to one of ordinary skill in the art that instant claim 13 and claims 1-8 of the '691 patent are substantially overlapping since both are drawn to the same structural features and have same utility.

Claim 13 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,764,998 ('998 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claim 13 is drawn to a bridged macrocyclic product obtained by the instant process. It is a product-by-process claim, which is a product claim.

Claims 1-21 of the '998 patent are also drawn to a bridged macrocyclic product that are embraced by the bridged macrocyclic product of instant claim 13.

It would be obvious to one of ordinary skill in the art that instant claim 13 and claims 1-21 of the '998 patent are substantially overlapping since both are drawn to the same structural features and have same utility.

Claims 1-6, 8-11 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 10 of U.S. Patent No. 6,274,715 ('715 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claim 1 is drawn to a process for preparing a bridged macrocyclic product via reaction of a macrocyclic compound having at least two nucleophilic moieties with a bridging component. Dependent claims 2-6 and 8-11 recite limitations drawn to specifc macrolides and structural formulae with specific structural requirements.

Claims 8-9 of the '715 patent are also drawn to the preparation of a bridged macrolide antibiotic comprising the reaction of a macrolide (erythromycin derivative) comprising at least two nucleophilic groups with a bridging component (a diamine). The starting macrocyclic compound used in the process of copending claims 8-9 have the structural requirements that are recited in instant claims 1-6 and 8-11.

Instant claim 13 is drawn to a bridged macrocyclic product obtained by the instant process. It is a product-by-process claim, which is a product claim.

Claims 1-7 and 10 of '715 patent are also drawn to a bridged macrocyclic product that are embraced by instant claim 13.

It would be obvious to one of ordinary skill in the art that instant claims 1-6, 8-11 and 13 are substantially overlapping with claims 1-7 and 10 of the '715 patent since both are drawn to a product with same structural features and the process of instant claims 1-6 and 8-11 are broad and encompass the process steps recited in claims 8-9 of the '715 patent and are applicable for making a bridged macrocyclic compound as instantly claimed.

Claims 1-6, 8-11 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 10 of U.S. Patent No. 6,645,941 ('941 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claim 1 is drawn to a process for preparing a bridged macrocyclic product via reaction of a macrocyclic compound having at least two nucleophilic moieties with a bridging component. Dependent claims 2-6 and 8-11 recite limitations drawn to specifc macrolides and structural formulae with specific structural requirements.

Claim 10 of the '941 patent is also drawn to the preparation of a bridged macrolide antibiotic comprising the reaction of a macrolide (erythromycin derivative) comprising at least two nucleophilic groups with a bridging component (a diamine). The starting macrocyclic

compound used in the process of copending claims 8-9 have the structural requirements that are recited in instant claims 1-6 and 8-11.

Instant claim 13 is drawn to a bridged macrocyclic product obtained by the instant process. It is a product-by-process claim, which is a product claim.

Claims 1-7 and 10 of '715 patent are also drawn to a bridged macrocyclic product that are embraced by instant claim 13.

It would be obvious to one of ordinary skill in the art that instant claims 1-6, 8-11 and 13 are substantially overlapping with claims 1-7 and 10 of the '715 patent since both are drawn to a product with same structural features and the process of instant claims 1-6 and 8-11 are broad and encompass the process steps recited in claims 8-9 of the '715 patent and are applicable for making a bridged macrocyclic compound as instantly claimed.

Claim 13 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 13 of U.S. Patent No. 6,645,941 ('941 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claim 13 is drawn to a bridged macrocyclic product obtained by the instant process. It is a product-by-process claim, which is a product claim.

Claims 1-6 and 13 of the '941 patent are also drawn to a bridged macrocyclic product that are embraced by the bridged macrocyclic product of instant claim 13.

It would be obvious to one of ordinary skill in the art that instant claim 13 and claims 1-6 and 13 of the '941 patent are substantially overlapping since both are drawn to the same structural features and have same utility.

Claim 13 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 13 of U.S. Patent No. 6,355,620 ('620 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claim 13 is drawn to a bridged macrocyclic product obtained by the instant process. It is a product-by-process claim, which is a product claim.

Claims 1-6 and 13 of the '620 patent are also drawn to a bridged macrocyclic product that are embraced by the bridged macrocyclic product of instant claim 13.

It would be obvious to one of ordinary skill in the art that instant claim 13 and claims 1-6 and 13 of the '620 patent are substantially overlapping since both are drawn to the same structural features and have same utility.

Claim 13 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,054,435 ('435 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claim 13 is drawn to a bridged macrocyclic product obtained by the instant process. It is a product-by-process claim, which is a product claim.

Claims 1-11 of the '435 patent are also drawn to a bridged macrocyclic product that are embraced by the bridged macrocyclic product of instant claim 13.

It would be obvious to one of ordinary skill in the art that instant claim 13 and claims 1-11 of the '435 patent are substantially overlapping since both are drawn to the same structural features and have same utility.

Claims 1-6, 8-10, 12 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,075,133 ('133 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claim 1 is drawn to a process for preparing a bridged macrocyclic product via reaction of a macrocyclic compound having at least two nucleophilic moieties with a bridging component. Dependent claims 2-6 and 8-10 and 12 recite limitations drawn to specifc macrolides and structural formulae with specific structural requirements.

Claims 4-5 of the '133 patent are also drawn to the preparation of a bridged macrolide antibiotic comprising the reaction of a macrolide (erythromycin derivative) comprising at least two nucleophilic groups with a bridging component (a diamine). The starting macrocyclic compound used in the process of claims 4-5 of the '133 patent have the structural requirements that are recited in instant claims 1-6 and 8-10 and 12.

Instant claim 13 is drawn to a bridged macrocyclic product obtained by the instant process. It is a product-by-process claim, which is a product claim.

Claims 1-3 and 6-7 of the '133 patent are also drawn to a bridged macrocyclic product that are embraced by instant claim 13.

It would be obvious to one of ordinary skill in the art that instant claims 1-6, 8-10, 12 and 13 are substantially overlapping with claims 1-7 of the '133 patent since both are drawn to a product with same structural features and the process of instant claims 1-6, 8-10 and 12 are broad and encompass the process steps recited in claims 4-5 of the '133 patent and are applicable for making a bridged macrocyclic compound as instantly claimed.

Claims 1-6, 8-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5-8 and 9-19 of U.S. Patent No. 6,046,171 ('171 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claim 1 is drawn to a process for preparing a bridged macrocyclic product via reaction of a macrocyclic compound having at least two nucleophilic moieties with a bridging component. Dependent claims 2-6, 8-12 recite limitations drawn to specifc macrolides and structural formulae with specific structural requirements.

Claims 9-19 of the '171 patent are also drawn to the preparation of a bridged macrolide antibiotic comprising the reaction of a macrolide (erythromycin derivative) comprising at least two nucleophilic groups with a bridging component. The starting macrocyclic compound used in the process of claims 9-19 patent have the structural requirements that are recited in instant claims 1-6 and 8-10 and 12.

Instant claim 13 is drawn to a bridged macrocyclic product obtained by the instant process. It is a product-by-process claim, which is a product claim.

Claims 1 and 5-8 of the '171 patent are also drawn to a bridged macrocyclic product that are embraced by instant claim 13.

It would be obvious to one of ordinary skill in the art that instant claims 1-6 and 8-13 are substantially overlapping with claims 1, 5-8 and 9-19 of the '171 patent since both are drawn to a product with same structural features and the process of instant claims 1-6 and 8-12 are broad and encompass the process steps recited in claims 9-19 of the '171 patent and are applicable for making a bridged macrocyclic compound as instantly claimed.

Claims 1-6, 8-10, 12 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 5,922,683 ('683 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant claim 1 is drawn to a process for preparing a bridged macrocyclic product via reaction of a macrocyclic compound having at least two nucleophilic moieties with a bridging component. Dependent claims 2-6, 8-12 recite limitations drawn to specifc macrolides and structural formulae with specific structural requirements.

Claim 25 of the '683 patent are also drawn to the preparation of a bridged macrolide antibiotic comprising the reaction of a macrolide (erythromycin derivative) comprising at least two nucleophilic groups with a bridging component. The starting macrocyclic compound used in

the process of claim 25 of the '683 patent have the structural requirements that are recited in instant claims 1-6 and 8-10 and 12.

Instant claim 13 is drawn to a bridged macrocyclic product obtained by the instant process. It is a product-by-process claim, which is a product claim.

Claims 1-24 of the '683 patent are also drawn to a bridged macrocyclic product that are embraced by instant claim 13.

It would be obvious to one of ordinary skill in the art that instant claims 1-6, 8-10, 12 and 13 are substantially overlapping with claims 1-25 of the '683 patent since both are drawn to a product with same structural features and the process of instant claims 1-6, 8-10, 12 and 13 are broad and encompass the process steps recited in claim 25 of the '683 patent and are applicable for making a bridged macrocyclic compound as instantly claimed.

Instant claims 1-13 must recite limitations that are patentably distinct from those of the claims of the copending applications and patents cited above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-6 and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Or et al (US 5,780,605).

Or et al teach a process for making a bridged macrocyclic compound (formula II, col. 33) comprising the reaction of a macrocyclic compound (col. 33, formula at lines 30-40, has at least two nucleophilic groups) with bromotrifluormethane (bridging component, col. 33, lines 65-67) followed by acid treatment to yield the bridged product. This teaching meets the limitations of claim1. The macrocyclic compound of Or is a derivative of erythromycin and is an antibiotic (limitation of claims 2 and 3). The macrocyclic compound of Or (formula at coll. 33, lines 30-40) has a =V (moiety V is double bonded to carbon of the ring at the top right of the formula, wherein V can be =N-O-R^1 and R^1 can be a C_1-C_6 alkyl (unsubstituted saturated alkyl group). The macrocyclic compounds also has two sugar units attached to it. This teaching meets the structural limitations of instant claim 5, structure I, wherein one of U or V can be a hydrogen and the other is a sugar (O-cladinose; limitation of claim 11) and one of R_e and R_f can be a hydrogen and the other can be a methyl (limitation of claim 10. The macrocyclic compound of Or has an ethyl group attached to the carbon adjacent to the ring oxygen. This is the group L in structure I in instant claim 6.

Claims 1-3, 5-6, 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Or et al (WO 99/21864).

Or et al teach a process for making a bridged macrocyclic compound (formula 14, page 36) comprising the reaction of the macrocyclic compound of formula 1 (page 34, has at least two nucleophilic groups) with the bridging components H_2N-$(CH_2)_m$-A-B-D-X and $(CH_2)_2$-C=CH_2 (page 36, scheme 3) to yield the bridged product. This teaching meets the limitations of claim1. The macrocyclic compound of Or is a derivative of erythromycin and is an antibiotic (limitation

of claims 2 and 3). The macrocyclic compound of Or (formula 1, page 34) has two sugar units attached to it. This teaching meets the structural limitations of instant claim 5, structure I, wherein one of U or V can be a hydrogen and the other is a sugar (O-cladinose; limitation of claim 11) and one of R_e and R_f can be a hydrogen and the other can be a methyl (limitation of claim 10. The macrocyclic compound of Or has an ethyl group attached to the carbon adjacent to the ring oxygen. This is the group L in structure I in instant claim 6. It also has a second carbonyl group (at the top left of formula 1, page 34), which corresponds to X and Y in instant claim 5 taken together form a carbonyl group (limitations of instant claims 5 and 8).

Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Or et al (US 5,780,605).

Or et al teaches a bridged macrocyclic product (formula II in claim 8, col. 33). This product is seen to meet the limitations of instant claim 13.

Instant claim 13 is a product-by-process claim, which is a product claim. Product-by-Process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps.

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Joint Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Or et al (WO 99/21864)

Independent claim 1 is drawn to a process for the preparation of a bridged macrocyclic product comprising reacting a macrocyclic compound having at least two nucleophilic moieties with a bridging component optionally in the presence of a catalyst. Dependent claims 3-5, 7-8 and 10

Or et al teaches a process for making a bridged macrocyclic compound (formula 14, page 36) comprising the reaction of the macrocyclic compound of formula 1 (page 34, has at least two nucleophilic groups) with the bridging components H_2N-$(CH_2)_m$-A-B-D-X and $(CH_2)_2$-C=CH_2 (page 36, scheme 3) to yield the bridged product. The macrocyclic compound of Or is a derivative of erythromycin and is an antibiotic. The macrocyclic compound of Or (formula 1, page 34) has two sugar units attached to it. The macrocyclic compound of Or has an ethyl group attached to the carbon adjacent to the ring oxygen. This is the group L in structure I in instant claim 6. It also has a second carbonyl group (at the top left of formula 1, page 34), which corresponds to X and Y in instant claim 5 taken together to form a carbonyl group.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the process of Or to make a bridged macrocyclic product as instantly claimed since the starting material, the bridging component and the process steps as instantly claimed is seen to be taught in the prior art.

One of ordinary skill in the art would be motivated to use the process of the prior art for making a bridged macrocyclic compound since the process is art tested and gives good yields using relatively mild conditions. One of ordinary skill in the art would be motivated to extend

this to other macrocyclic compounds in order to develop new derivatives having improved antibacterial activity since there is a continuing need to identify new derivatives which may have less potential for developing resistance (Or, page 1, lines 15-20). One of ordinary skill in the art would also recognize that the process of making the bridged macrocyclic compound could be extended with a reasonable expectation of success to other derivatives of erythromycins since all of them have the same core structure and the required nucleophilic moieties.

Conclusion

Claims 1-13 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600